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Award Number: W81XWH-12-1-0576

TITLE: A Randomized, Controlled Trial of Meditation Compared to Exposure Therapy and Education Control on PTSD in Veterans

PRINCIPAL INVESTIGATOR: Sanford Nidich, Ed.D.,

CONTRACTING ORGANIZATION: Maharishi University of Management Research Institute, Maharishi Vedic City, Iowa 52556.

REPORT DATE: October 2013

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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14. ABSTRACT This single-blinded, RCT will: 1) evaluate effects of Transcendental Meditation (TM) vs. Prolonged Exposure (PE) and PTSD health education control (EC), using the Clinician Administered PTSD Scale (CAPS) (primary outcome); 2) evaluate effects of TM vs. controls on PTSD symptoms (PCL-M), depressive symptoms and other psychological distress measures, quality of life, and physiological/biochemical stress markers; and 3) evaluate treatment compliance. The study will enroll 210 subjects (70 per group). The VA San Diego is the field site with testing conducted at 0 and 3 months. The research will provide data on the feasibility and efficacy of TM as an alternative therapy for PTSD. Our collaborative group (Maharishi University of Management Research Institute, VA San Diego Healthcare System, University of California at San Diego) has made excellent progress in year one. Since securing IRB and DoD human subjects approvals the end of May 2012, we completed hiring all staff, finalized procedures for conducting the study, are currently on target for randomization, with 24 subjects randomized over the first four-months (target of 23) and have good treatment compliance, with over 80% treatment sessions attended. Our first Data Safety and Monitoring Board Meeting, chaired by our medical monitor, was held July 2013.					
15. SUBJECT TERMS PTSD, Meditation, Prolonged Exposure, Veterans					
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a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	17	USAMRMC
			19b. TELEPHONE NUMBER (include area code)		

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INTRODUCTION

Posttraumatic stress disorder (PTSD) is a common and debilitating condition that affects up to 20% of all Veterans¹⁻³. PTSD is often a chronic problem for Veterans, affecting reintegration into society, family and marital relationships, sleep, employment stability, substance abuse rates, and risk for depression and suicide^{4, 5}. Although standard treatments exist to treat PTSD, research shows that up to 50% of patients continue to have elevated symptoms^{5, 6}. This suggests a need for developing and evaluating additional, alternative treatment options.

We are currently engaged in a collaborative research project that includes Maharishi University of Management Research Institute, VA San Diego Healthcare System, and the University of California at San Diego. This single-blinded, randomized controlled trial (RCT) will: 1) evaluate effects of Transcendental Meditation (TM) vs. Prolonged Exposure (PE) and a PTSD health education control (EC), using the Clinician Administered PTSD Scale (CAPS), as the primary outcome; 2) evaluate effects of TM vs. controls on PTSD symptoms (PCL-M), depressive symptoms and other psychological distress measures, quality of life, and physiological/ biochemical stress markers; and 3) evaluate treatment compliance. The study will enroll 210 subjects (70 per group) over four years. The intervention period for each arm is three months, with testing conducted at 0 and 3 months.

The research will provide important data on the feasibility and efficacy of the Transcendental Meditation program as an effective alternative therapy for PTSD. The results will serve to inform policy decisions on the study and application of this standardized and validated stress reduction program in Veteran populations.

BODY

The following tasks describe the actual Year 1 (Oct 1, 2012 thru Sept 30, 2013) achievements/milestones compared to the tasks originally outlined in the Statement of Work (SOW) (July, 2012, final-revised)

Task 1: Regulatory Review and Approval Processes (Completed)

Final DoD ORP approval was given for our staff to begin recruitment on May 31, 2013. This approval came after we made several human subjects-related adjustments based upon DoD ORP requests. The most significant of these requests involved receiving approval from the VASDHS IRB to do consenting over the phone prior to conducting initial phone screens. All subjects complete written informed consent, approved by the local IRB and DoD ORP, prior to baseline testing.

Task 2: Hiring and Training of Staff (Completed)

We completed the hiring and training of our three full-time staff coordinators. After final approval from the DoD ORP, we were also able to officially hire the Prolonged Exposure study therapist – allowing us to have all of our study therapists in place.

Task 3: Development of Case Report Forms and Operation and Treatment Manuals (Completed)

We completed Case Report Forms and Operation and Treatment Manuals prior to beginning the study June 2013.

Task 4: Recruitment of Study Subjects (Consistent with Target Number)

After final DOD approval on May 31, 2013, we began recruitment of subjects. Over the initial four-month period, starting June 2013, we randomized (enrolled) 24 subjects, with a target goal of 23 (5.8 per month x 4 months). To date, there have been 82 phone screens, 38 consented (written consents), 24 completing baseline testing and eligible for enrollment, and 24 randomized. Figure 1 in the Supporting Data section illustrates the trend of randomized subjects.

Recruitment methods have included the use of posters, flyers, presentations to Veterans groups and community centers, placing information in VA and Veterans newsletters and presenting the study to VA healthcare providers for referrals. In August, we also purchased advertising space in local San Diego newspapers that contain sections targeting military populations. Weekly teleconference meetings are held on an ongoing basis with all staff and investigators, led by the initiating and partnering PIs.

Task 5: Testing of Subjects – baseline and 3-month post-testing (on target)

Baseline testing began June 2013. From June thru September 2013, 24 subjects, meeting eligibility criteria and completing baseline testing, were randomized (two-thirds of the subjects are males, one-third female; mean age= 46.43). Three-month posttesting for the first cohort will begin in October 2013.

The baseline table for most of the major study outcomes for subjects randomized through September 30 is presented in the Supporting Data section of this report. Biomarkers were not included since lab reports were not yet available for this report. The data is presented by treatment arm in a blinded manner since this is a single-blinded phase two trial. No significant differences among the three treatment arms were observed on the study outcome measures (all p values > .05).

Task 6: Delivery of Treatments (on target)

Through the end of September, 24 subjects have been randomized which meets our target goal. Of these, 92% of the randomized subjects have gotten into treatment or were scheduled for their first treatment session to begin the first week of October. One subject cancelled and one unexpectedly had to go out of town before treatment could begin. Treatment sessions are held at the VASDHS for all treatment arms and last approximately 60-75 minutes. Sessions are provided by trained instructors in each of the treatment arms: Transcendental Meditation, Prolonged Exposure, and PTSD Health Education, and are supervised by the research team for quality control.

No adverse events have been reported to date.

Task 7: Treatment Compliance (on target)

Overall approximately 80% of the treatment sessions held through September 30 have been attended. Treatment sessions are held at the VASDHS for all treatment arms and last approximately 60-75 minutes. Sessions are provided by trained instructors in each of the treatment arms: Transcendental Meditation, Prolonged Exposure, and PTSD Health Education, and are supervised by the research team for quality control. For home practice, approximately 90% of subjects have indicated compliance with their home practice program. These figures are above the 70% milestone established.

Task 8: Data Entry and Management (on target)

The Access database for data entry at VASDHS was developed and completed by study statistician, Maxwell Rainforth, and pilot tested by the VA data manager in Spring 2013. Study data collection, processing and data entry began June 2013 with the first cohort. Data entered and stored is under strict quality control procedures. All baseline data have been collected and entered, except for the biomarker data, which will be processed by the study lab at a later date. Post-testing is scheduled to begin October 2013. This meets our milestone established of 100% of collected data being entered.

Task 9: Data Analysis (on target)

Baseline data is presented in the Supporting Data section of this document. The data is presented by treatment arm in a blinded manner. No significant differences among the three treatment arms were observed on the study outcome measures (all p values > .05). Post-test data has not been collected as of this report. Data analysis procedures are on target.

Task 10: Overall Project Management (on target)

The initiating PI, Dr. Nidich at MUMRI, and partnering PI, Dr Rutledge at VASDHS, and their teams along with Dr. Mills at UC San Diego have been engaged in weekly teleconference calls since the first month of the award, October 2012. In addition, Dr. Nidich and Dr. Rutledge frequently communicate each week on study management issues by phone and email. Other group members and staff have also frequently communicated by email and phone on a regular basis on study implementation issues, supervised by Drs. Nidich and Rutledge. Group conference calls with PIs, investigators, and staff will be ongoing throughout the trial.

Dr. Nidich from MUMRI made a site visit in July 2013 to VASDHS and had several important meetings with Dr. Rutledge, Dr. Mills, study staff, and treatment providers.

Drs. Nidich, Rutledge, and Mills attended the first Data Safety and Monitoring Board (DSMB) meeting, held in San Diego and chaired by the study's medical monitor Dr. Charles Elder, M.D. Other members of the DSMB include Dr. Kerri Boutelle, psychologist, Dr. Arpi Minassian, psychologist, and Dr. Loki Natarajan, biostatistician. The minutes of the meeting and decisions made by the DSMB are included in the Appendix section of this report.

Task 11: Quarterly and Annual Reports

This document represents the study's first Annual report. Previously in Year 1, all three quarterly reports to the DoD were written, submitted and received in a timely manner.

KEY ACCOMPLISHMENTS

- Study recruitment began in June 2013 immediately following DOD ORP human subjects approval.
- All study staff and treatment therapists have been hired and trained as of the end of May 2013.
- As of Sept 30, 2013, 24 subjects have been randomized, which meets our target goals for the first four months of the study.
- We assembled a four-member Data Safety and Monitoring Board (DSMB) to oversee our study, with the panel meeting on July 18, 2013 in San Diego to

review our study protocol. The DSMB membership is chaired by Dr. Charles Elder, M.D., the study's medical monitor, and includes two clinical psychologists, who are active researchers and faculty at the UC San Diego Dept of Psychiatry and a biostatistician with the Dept. of Family and Preventive Medicine at UC San Diego

- A member of our VA research team, fulltime study coordinator Erika Matthews, attended the 2013 Military Health Research Forum in Ft. Lauderdale, Florida.

REPORTABLE OUTCOMES

There were no manuscripts, abstracts or presentations in Year 1.

CONCLUSION

This report summarized the study progress over Year 1. We are meeting all of our Statement of Work targets for the study. Study recruitment began on June 2013 immediately following DoD ORP human subjects approval. All study staff and treatment therapists have been hired and trained, operation manuals completed, and baseline testing and treatment sessions started. As of the end of September 2013, 24 subjects have been randomized, which meets our target goals for the first four months of the study. A Data Safety and Monitoring Board (DSMB) has been formed, chaired by the study's medical monitor, Dr. Charles Elder M.D., with the DSMB's first meeting being held on July 18, 2013 in San Diego. There have been no "substantive" amendments to the study protocol. There were no adverse events to date.

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4. Kessler RC. Posttraumatic stress disorder: The burden to the individual and to society. *J Clin Psychiatry.* 2000;61 Suppl 5:4-12; discussion 13-14
5. Kessler RC, Sonnega A, Bromet E, Hughes M, Nelson CB. Posttraumatic stress disorder in the national comorbidity survey. *Arch Gen Psychiatry.* 1995;52:1048-1060
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APPENDICES

The following documents are included in this section of the report:

Appendix 1: Data Safety and Monitoring Board Minutes

Appendix 2: Edited Study Flyer Approval by VASDHS IRB

Appendix 3: Additional Treatments Following Completion of Three-Month Study

Approval by VASDHS IRB

(Note: Concerning this amendment to the study, since funds for additional instruction for those having completed the three-month study were raised from a private foundation to cover the cost of instruction, we were sent an email from Karen Eaton explaining that we did not need additional DoD approval for this modification.

The revised written informed consent (approved by VASDHS IRB August 12, 2013) states: After completing this three-month study, you will be eligible to receive additional treatments. These additional treatments include referrals to the several individual and group PTSD services within the VA San Diego Healthcare System. In addition, if you are not assigned to the Transcendental Meditation treatment as part of the study, would like to receive this treatment, and complete at least eight of the twelve sessions of the treatment to which you are assigned, we will arrange for you to receive meditation training at the Transcendental Meditation center, located in Encinitas, at no cost to yourself.

Karen Eaton's email response to our inquiring whether the DoD needs to further approve this amendment (Karen M. Eaton, M.S., Human Subjects Protection Scientist (General Dynamics Information Technology) Human Research Protection Office (HRPO) Office of Research Protections (ORP) United States Army Medical Research and Materiel Command (USAMRMC) Fort Detrick, Maryland):

Classification: UNCLASSIFIED, Caveats: NONE

Hi Tom,

I appreciate you notifying the DoD of this change to your study. However, if you are adding this option to your study using private funds, then the DoD does not need to review or approve the change. We are only required to review the research procedures paid for by your DoD award. So as long as you have local IRB approval for this change, you are good to go.

I will ask that you include this modification in your continuing review submission to us. Your award requires that substantive modifications be submitted for approval in real time, however, other minor modifications can wait until your continuing review to be reported. As this modification falls outside our purview, I would consider it minor for DoD purposes.

Please do not hesitate to contact me with any questions or concerns.

Sincerely,

Karen

Appendix 1: Data Safety and Monitoring Board Minutes (07/18/13)

Data and Safety Monitoring Board meeting minutes 7/18/2013

Attendees: Charles Elder, Kerri Boutelle, Arpi Minassian, Loki Natarajan, Thomas Rutledge, Sanford Nidich, Paul Mills, Mayra Gomez, Maxwell Rainforth (via phone)

- Introduction
- Review of DSMB charter
 - The DSMB charter was reviewed by and unanimously approved by the committee
Reports at future meetings may encompass recruitment, safety, and other relevant data. It was specified that at this time the DSMB does NOT anticipate requiring interim reports of efficacy data.
- Review of conflict of Interest and Confidentiality statement. Board members are to review and sign this document.
- Review of Project Narrative
 - Overview: A single blinded, randomized controlled clinical trial of Transcendental Meditation (TM), Prolonged Exposure Therapy (PE), and Post-Traumatic Stress Disorder (PTSD) Health education (HE) control on PTSD in veterans. Participants will undergo a 3 month intervention treatment in one of the three treatment arms. The primary outcome is a change on the Clinician Administered PTSD Scale (CAPS). Secondary outcomes include self-report assessments of PTSD Checklist – Military version (PCL-M), depression scale Patient Health Questionnaire (PHQ-9), Profile of Mood States (POMS), and Quality of life Enjoyment and Satisfaction Questionnaire short form (Q-LES-Q-SF). Testing will be performed at baseline and 3 month follow up, post intervention period.
 - A proposed sample size of 210 men and women; inclusion criteria are as follow: 1) 18 year or older. 2) Current medical diagnosis of PTSD through symptom severity score of 45 or higher on the CAPS. 3) Three or more months since service related trauma, 4) Agreement to not receive psychotherapy or cognitive therapy, or other meditation therapy for PTSD during the 3-month study treatment. Psychotherapy for other problems is allowed. 5) If being treated with psychoactive medication, a stable regimen (no change in drugs or dose) for at least 2 months before enrollment. Participants are excluded from participating for any of the following: 1) Current psychotic symptoms, mania or bipolar disorder. 2) Current suicidal or homicidal ideation. 3) Moderate or greater cognitive impairment indicated by chart diagnosis, observable cognitive difficulties, and upon the Saint Louis University Mental State questionnaire (SLUMS).
 - Q: Are there any common PTSD medications known to interfere with PE treatment?
 - No known medication have been proven to affect PE treatment, though some participants will be on antipsychotic, antianxiety, and antidepressant medications.

- Since recruitment began in June, the research team had a total of 32 initial phone screens, 18 eligible upon screen, 13 completed BLT (5 scheduled for BLT), and 8 individuals are currently randomized.
 - ~ 56% individuals are eligible upon phone screen
- Expanding inclusion criteria beyond military- related PTSD
 - Current inclusion criteria specifies that traumatic event needs to have occurred during the time of active duty (military related or not). The proposed change would allow for a veteran with PTSD related to any traumatic event (for example, a childhood trauma) to be considered for inclusion. If implemented this change would necessitate use of the PCL-C/PCL-S instead of the PCL-M as an outcome measure.
 - Reasons for change
 - No data specifies efficacy of treatment varying from type of PTSD
 - VA currently treat veterans with non-military PTSD
 - Competition with current VA PTSD studies may hinder recruitment
 - Reasons against change
 - Generalizing criteria may add too much variability when analyzing results
 - Unknown delay from the DOD IRB
 - The DSMB approves implementing this change at the discretion of the Principal Investigator , should issues with recruitment so require.
 - Comment: If these new criteria are implemented, the study team might consider possible refinements to design: for e.g., should they stratify randomization by type of traumatic event (during active duty vs not)? This is a decision that the Study team needs to make based on implications of the expanded inclusion criteria, and possible differential efficacy of TM and other treatments by type of trauma.
- New incentive: Bonus treatment option after completion of study
 - The bonus treatment incentive would permit offering a participant any one of the other two study interventions, after the participant completes the study, if the participant so requests. For example, a participant randomized to HE could, after completing the HE interventions and follow up data collection, be provided with PE or TM therapies, as per his or her preference. Likewise, a TM participant could receive PE, or a PE participant could receive TM, after study completion.
 - Bonus Transcendental Meditation instruction, or PE, would be offered to participants who wish to seek TM or PE treatment, only after they complete all baselines, post-tests, and a minimum of 8 assigned treatment groups when enrolled.
 - The bonus TM instruction would be paid by a separate funding source from DOD grant
 - When participant completes minimum requirements in the study, he/she will be directed to TM instructors in Encinitas, or PE therapy @ The VA, per the participant's preference. Research staff will have no contact with individual at that point, and no further data will be collected.
 - Offering to individuals as long as they complete 8 treatment sessions
 - Good incentive that will aid attrition rate
 - Q: What if a TM enrolled participant decides to continue TM after they complete their participation?
 - TM students are welcomed to attend classes at any TM center thereafter, and continue practice.

- DSMB members approve the new bonus treatment incentive, and PI's will work on making changes with the IRB.
- Q: Are there any protocols that closely monitor for suicidal ideation in this sensitive population?
 - Suicidal Ideation (SI) is monitored on the Patient Health Questionnaire (PHQ-9), item # 9. This measure is given at baseline, interim visits, and at post-testing. If participant reports a low severity of SI, the staff will inform the Dr. Thomas Rutledge, and he will call participant within 24-hours to monitor their status. If participant reports moderate to severe SI, research staff will accompany participant to emergency psychology services, located at the VA for further evaluation. If SI intensifies during their participation, PI's may decide that participation is not in their best interest, and seek aid for individual.
- Managing randomization in groups
 - Target monthly goal: Randomizing 6 participants per month over next 36 months of the trial
 - DSMB members are concerned of the lag time between randomization and start of treatment sessions, thus increasing attrition.
 - Health education control may teach individual classes until a group is formulated. Rolling groups will allow new enrollees to start at any stage.
 - Transcendental Meditation is best taught in groups (>3), however some classes may be taught individually due to difficulties enrolling more than 8 individuals per month.
 - DSMB members agree that a maximum 10- day period between randomization and start of treatment is acceptable.
 - Current randomization is conducted in a cohort of 3
 - Alternatives randomization schemes, such as cluster randomization in blocks, were reviewed.
- Reviewed format of tables developed by study statistician

DSMB committee approved data table format presented by study statistician to be used in future meetings
- Review of Adverse Event form
 - Given out every few weeks,
 - In the course of any serious study related adverse event, research team will inform Dr. Elder right away. The rest of the DSMB members will be informed by Dr. Elder, and group discussion will take place if necessary.
 - The report table 4.1 Summary of adverse events and actions should include an attrition percentage variable, and where drop out occurs.
 - ~30 % is the estimated attrition percentage for the given population
 - Copies of individual adverse event forms will be available to Dr. Elder for review and discussion at future DSMB meetings.
- Summary of decisions:
 - Expanding inclusion criteria beyond military- related PTSD should be implemented if deemed appropriate by Principal Investigators
 - Bonus treatment incentive option is approved
 - Randomization will be conducted immediately, and treatment will be initiated within 10 days after randomization.

- Next meeting will be in six months. Team will decide if meeting will take place in person or via conference call (anticipate this will be a conference call unless some circumstance dictates otherwise).

Meeting adjourn

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles R. Elder".

Charles Elder MD MPH FACP
DSMB Chair

Appendix 2: Edited Study Flyer Approval by VASDHS IRB

August 12, 2013 To: Thom as R Rutledge

Re: IRB Protocol # H120042 A RANDOM IZED , CONTROLLED TR IAL
OF MEDITATION COMPARED TO EXPOSURE THERAPY AND
EDUCATION CONTROL ON PTSD IN VETERANS

Dear Dr. Rutledge

Your 08/08/2013 08:05:47 PM PDT request to amend IRB protocol H120042 was reviewed and approved on 08/12/2013. This amendment included the following:

A new study recruitment flyer that contains a pair of small changes from the previously IRB- approved flyer. Specifically, the new flyer changes the listed study contact number (previously 7075) to extension 5979. The new contact number reaches the same research laboratory supervised by Dr. Rutledge, but will allow prospective participants to reach a condition-blinded research assistant that we prefer to use for the initial phone screens.

This amendment was reviewed and approved by the expedited review process as authorized by 38 CFR 16.110(b)(2) and VHA Handbook 1200.05 Paragraph 18a(2) following VASDHS SOPP 37 Chapter 15 Section 1.4. In the judgment of the IRB the changes do not affect the assessment of the risks and benefits of the study by substantially altering any of the following: research aims or methodology, nature of subject participation, level of risk, proposed benefits, participant population, qualifications of the research team, or the facilities available to support the safe conduct of the research.

Please note that the amendment approval date does not alter the study expiration date. A modification is given approval only to the expiration date that was received at the most recent initial or continuing review. Also, please check your most recent initial or continuing review approval letter and sure that continuing review materials are submitted approximately 45 days prior to that expirations. If this amendment modified the Informed Consent or HIPAA Authorization, the newly approved versions will be those stamped with the current approval date noted above.

Thank you for keeping us informed. On behalf of the Institutional Review Board

William Penny, M.D. Chair, VASDHS IRB

DEPARTMENT OF VETERANS AFFAIRS VA San Diego Healthcare System 3350 La Jolla Village Dr. San Diego, CA 92161

Human Research Protection Program Institutional Review Board



cc: R&D Committee

Appendix 3: Additional Treatments Following Completion of Three-Month Study
Approval by VASDHS IRB

August 12, 2013 To: Thom as R Rutledge

Re: IRB Protocol # H120042 A RANDOM IZED, CONTROLLED TRIAL
OF MEDITATION COMPARED TO EXPOSURE THERAPY AND
EDUCATION CONTROL ON PTSD IN VETERANS

Dear Dr. Rutledge

Your 06/17/2013 06:51:15 PM PDT request to amend IRB protocol H120042 was reviewed and approved on 07/16/2013 [Approval released 08/12/2013]. This amendment included the following:

- 1) The revised consent (6-17-13 version) contains two changes from our currently IRB approved consent: a) On the bottom of page 3, section 5, we now specify the storage of the treatment session recordings on the R drive (this change was requested in the 5-16-2013 IRB review);
- 2) On page 4, section 6, 2nd paragraph, we now include language offering free transcendental meditation training (the commercial cost of this is about \$1,450 but we've obtained private industry funding to pay for participant's costs) if they complete their assigned study treatment. We believe that the availability of this offer will assist with study recruitment and retention, as the meditation treatment is expected to be popular. However, we appreciate the possibility of this being seen as coercive.
- 3) In parallel to the above, we have amended sections of the IRIS project application to refer to the same changes (storage of the treatment session videotapes and offering of meditation treatment to study completers). This includes additional text added to sections 16 and 20 of the IRB application.

This amendment was reviewed and approved by the expedited review process as authorized by 38 CFR 16.110(b)(2) and VHA Handbook 1200.05

Paragraph 18a(2) following VASDHS SOPP 37 Chapter 15 Section 1.4. In the judgment of the IRB the changes do not affect the assessment of the risks and benefits of the study by substantially altering any of the following: research aims or methodology, nature of subject participation, level of risk, proposed benefits, participant population, qualifications of the research team, or the facilities available to support the safe conduct of the research.

Please note that the amendment approval date does not alter the study

expiration date. A modification is given approval only to the expiration date that was received at the most recent initial or continuing review. Also, please check your most recent initial or continuing review approval letter and sure that continuing review materials are submitted approximately 45 days prior to that expirations. If this amendment modified the Informed Consent or HIPAA Authorization, the newly approved versions will be those stamped with the current approval date noted above.

Thank you for keeping us informed.

DEPARTMENT OF VETERANS AFFAIRS VA San Diego Healthcare System 3350 La Jolla Village Dr. San Diego, CA 92161

Human Research Protection Program Institutional Review Board

On behalf of the Institutional Review Board

William Penny, M.D. Chair, VASDHS IRB

cc: R&D Committee

A handwritten signature in black ink, appearing to read "WP".

SUPPORTING DATA

Figure 1: Trend of Randomized Subjects Over the First Four Months

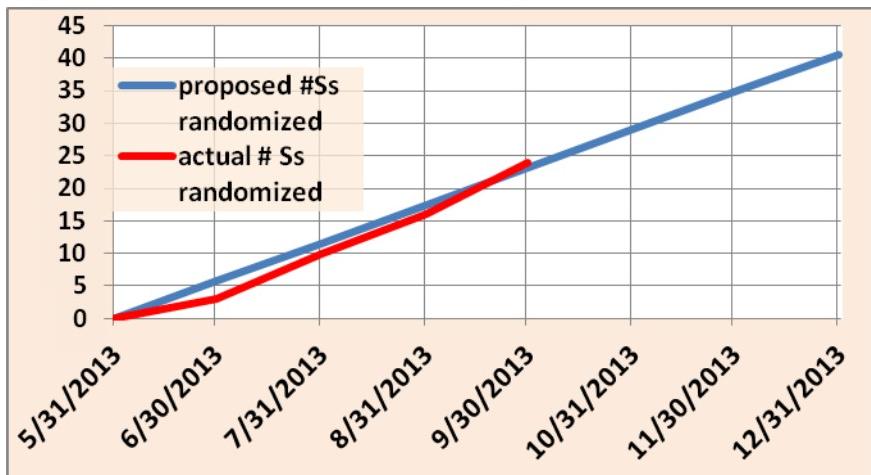


Table 1: Baseline Study Outcomes by Treatment Arm

Variable	Group 1 N=9		Group 2 N=8		Group 3 N=7		P-value
	Mean	SD	Mean	SD	Mean	SD	
Primary Outcome: Clinician Administered PTSD Scale (CAPS)	89.7	20.2	81.1	19.4	84.3	17.6	0.656
Secondary Outcomes: PTSD Checklist – Military Version (PCL-M)	68.1	7.7	59.8	14.2	62.3	6.6	0.238
Depressive Symptoms (PHQ-9)	17.1	6.2	19.1	5.3	16.6	4.1	0.622
Quality of Life: (LES Q - SF)	38.7	7.0	41.3	15.8	38.0	18.0	0.887
Alcoholic drinks, number past week	1.4	3.0	1.7	2.8	6.0	10.3	0.282
Social Support Scale (SSS): Number of sources of support	8.7	6.7	16.0	19.0	16.6	17.7	0.497
SSS: Satisfaction with support	23.0	10.3	23.3	9.1	26.4	9.0	0.745
Combat Exposure Scale	18.6	11.5	6.5	14.2	15.0	11.7	0.155
Life Events Checklist	7.3	2.8	8.9	4.3	10.0	3.3	0.323
Systolic blood pressure, mm Hg	119.7	13.2	132.3	18.2	139.9	20.6	0.082
Diastolic blood pressure, mm Hg	76.1	12.8	86.6	8.6	82.5	10.2	0.154
Weight, kg	90.6	17.2	97.4	18.7	84.6	18.7	0.406
Body mass index	31.1	3.4	32.2	5.9	28.8	7.4	0.528